K002812

NOV - 8 2000

Michael Reynard, M.D.
1301 – 20th Street #260
Santa Monica, CA 90404
310-453-0551

510(k) Summary per section 807.92(c)

Submitter's Name: Michael Reynard, M.D.
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Contact Person: Michael Reynard, M.D.
Date of Summary: 8/10/2000

Name of Device: Surgical Instrument Sleeve

Tradename of Device: Iris Retracting Phacoemulsification Sleeve

Equivalence: The subject device substantially incorporates predicate sleeves with a minor alteration that provides manipulation of intraocular tissue.

Description of Device: Surgical instrument sleeve for phacoemulsification surgery.

Intended Use of Device: Provide enhanced ability for surgeon to manipulate intraocular tissue.

Comparison with predicate devices: Medical grade plastic surgical sleeves with Class II classification devices are used for phacoemulsification/cataract surgery. Construction materials are identical with existing surgical instrument sleeves that are legally marketed devices currently in widespread use. Colors are identical to those legally marketed devices currently in use.

General Sterilization Method: Autoclave for surgical instrument sleeve.

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LABELING OF SURGICAL INSTRUMENT SLEEVE

The enclosed device is STERILE and NON-PYROGENIC (unless the package has been opened or damaged).

FOR SINGLE USE ONLY. NOT RETURNABLE IF OPENED

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician.

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METHODS OF STERLIZATION AND DISINFECTION

Methods for cleaning and sterilization of the surgical instrument sleeve are the same as that which is currently used on predicate device. Methods of sterilization includes:

A) GRAVITY DISPLACEMENT STEAM STERILIZATION:
For standard sterilization methods, reference Association for the Advancement of Medical Instrumentation (AAMI) Standards and Recommended Practices Volume 1: Sterilization, (1998) Designation ST37, section 5.4: Designation SSSA, section 4.6. This method has achieved a sterilization assurance level of 10^-6.

1) Surgical instrument sleeve(s) are placed in an open position on a perforated sterilization tray or container.
2) A sterilization indicator is placed in each tray or load.
3) Load specification is for 270 degrees F. (30 psi) for Ten (10) minutes.
4) Conditions of sterilization are verified from the paper printout and chemical indicator on completion of the cycle.

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B) GAS STERILIZATION: For gas sterilization, reference AAMI Standard Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use (March 1995, Draft Revision) Designation ST37R-D395.

C) STERIS CHEMICAL STERILIZATION is performed by personnel trained according to the following guidelines:

1) A diagnostic cycle is run each day to determine sterilizer readiness.
2) Clean surgical instrument sleeve(s) are placed in the open position in the STERIS container.
3) A new chemical activator is inserted into the sterilization chamber prior to initiation of the preset cycle.
4) Conditions of sterilization are verified from the paper printout on completion of the cycle.

C) FLASH STERILIZATION

This method is reserved for emergency situations only. For standard sterilization, reference AAMI Standard Flash Sterilization: Steam Sterilization of Patient Care Items for Immediate Use (March 1995, Draft Revision) Designation ST37R-D395.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Michael Reynard, M.D.
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Re: K002812
Trade Name: Surgical Instrument Sleeve
Regulatory Class: II
Product Code: 86 HQC
Regulation: 886.4360
Dated: September 3, 2000
Received: September 8, 2000

Dear Dr. Reynard:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-6413. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Michael Reynard
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Santa Monica, CA 90404

510(k) Number (if known):

Device Name: SURGICAL INSTRUMENT SLEEVE

Indications For Use:

ACCESSORY INFUSION SLEEVE
FOR CATARACT SURGERY WHICH
ALSO PROVIDES RETRACTION OF IRIS

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Gary Constanzo

(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number K002812

Prescription Use ✓ OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)